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DETAILED ACTION

Status of Claim

Claims 2, 4, 6-9, 11, 35, 36, 40 and 41 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 2, 4, 6-9, 11, 35, 36, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons reiterated below only for the maintained rejection.

1. Claim 2 is indefinite as to the "portion of copper of the core" that reacts with pyrithione i.e., whether the portion refers to the amount/concentration or what constitutes the differentiating feature of portion of a core.

Response to Arguments

Applicants argue that inasmuch as only the copper in the surface portion of the core materials is available for the transchelation reaction with pyrithione acid or a water-soluble salt of pyrithione, the meaning of "a portion of" is not indefinite because a person skilled in the art would readily understand that it refers to the copper in the surface portion

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of the core. Similarly, claim 41 satisfies the written description requirement.

In reply, firstly the rejection is not a written description rejection under an indefiniteness issue. Secondly, "a portion of", given a reasonable interpretation of the claim, would indicate not the whole copper present in the copper-containing compound, rather only a portion of the copper contained in the compound. It is suggested that applicants amend the claim "a portion of copper" to --the copper of said copper-containing compound---.

2. Withdrawn in view of the amendments to claims 6-9.

Double Patenting

Claims 2, 4, 6-9, 11, 35, 36, 40 and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over e.g., claim 3 of U.S. Patent No. 7026308 ('308 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '308 Patent is an obvious variant of the instant claimed composition for reasons repeated below.

Claim 3, for example, of the '308 Patent recites a composition comprising a polyvalent metal salt of pyrithione selected from the group consisting of zinc pyrithione, copper

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pyrithione, and mixtures thereof. The instant composition uses the terms shell and core to describe the components of the composition as pyrithione and copper, respectively. The similar components, if not the same, pyrithione and copper is disclosed by '308 Patent. Thus, the form by which the components exist in a composition is immaterial as the components of the composition are similar, if not the same. The '308 Patent discloses throughout the patent that the polyvalent metal salts of pyrithione are known to be effective biocidal agents and are widely used as fungicides and bacteriocides in paints and metalworking fluids. Polyvalent metal salts of pyrithione are also used as fungicides and bacteriocides in personal care compositions such as foot powders and anti-dandruff shampoos. The polyvalent metal salts of pyrithione are only sparingly soluble in water and include, inter alia, copper pyrithione. '308 Patent discloses that the metal ion source is present in the composition at a ratio to polyvalent metal salt of pyrithione of from about 5:100 to about 5:1; preferably from about 2:10 to about 3:1; more preferably from about 1:2 to 2:1.

Response to Arguments

Applicants acknowledge that Gavin et al. relates to a topical composition for treating microbes comprising: a) an anti-microbial active selected from the group consisting of

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polyvalent metal salts of pyrithione; b) a metal ion source, which can be copper salts; and c) a topical carrier for the anti-microbial active and the metal salt. But traverse in that an important feature of the compositions recited in the claims of Gavin et al. is that those compositions mandates the presence of at least a 5 to 1 ratio of polyvalent metal salt of pyrithione to a strong chelating agent wherein the strong chelating agent is selected from the group consisting of di- or polyamines, diethylene triamine penta-acetic acid, tetraethylene triamine, ethylene diamine, diethylene triamine or salts thereof or mixtures thereof. In contrast, the instant claims are not directed to the presence or absence of any strong chelating agent. Rather they are directed to biocidal compositions comprising composite particles.

In response, applicants used of the word "comprising" does not preclude the presence of other components present in the prior art formulation i.e., strong chelating agent. It has been long held that the use of the term "comprising" leaves a claim open for inclusion of materials or steps other than those recited in the claims". Ex parte Davis, 80 USPQ 448.

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Claim Rejections - 35 USC § 102/103

Claims 2, 4 and 6-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hosseini et al. US Pat. No. 5,540,860 (7/96) alone or if necessary further in view of the specification {e.g. page 7, figures (e.g. fig. 2) and examples (e.g. example 1) to demonstrate inherency (e.g. see Ex parte Novitski, 26 USPQ2d 1389 (B.P.A.I, 1993); MPEP 2131.01(d).

Hosseini teaches a "biocidal composition" (e.g. see col. 1, especially lines 45-50) comprising "particles" of "copper pyrithione" formed by aqueous mixing: (a). "a copper compound" (e.g. a "copper salt" such as copper chloride or copper sulfate) and (b), "a pyrithione salt" (see col. 2, example 1). The Hossein et al. method teaches the use of pyrithione salts between about 1 to about 40% (based on total composition weight), between 5 and 25% and 15 and 25% (e.g. see Hossein at col. 2, especially lines 54-60)which anticipates, or alternatively renders obvious the percentage amounts of copper pyrithione adduct shell of present claims 7- 9, respectively. since the reference amounts are within the scope of the claimed amounts. The Hossein teaching of "between about one and about 40% of the pyrithione salt" would anticipate or render obvious

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the corresponding copper/copper compound amount of "about 99% to about 60%" as presently claimed in claim 4; and additionally, the proportions of the Hossein components (e.g. see bottom of col.2) are within the scope of the wide ratio proportion (1:20 to 20:1) of core/shell ingredients. Hosseini teach the optional surfactant coating of its particles (e.g. see col. 2, lines 10-17). To the extent that the Hossein reference biocidal copper pyrithione (e.g. spherical) particles differ by failing to explicitly teach the physical nature of the resulting particle e.g. a copper pyrithione "shell" and copper/copper compound "core" such a physical arrangement MUST be inherently present in the Hossein particles since: (a). The Hossein particles are composed of the same ingredients and in the same amounts as the presently claimed particles; (b). The Hossein particles are formulated in the same manner (compare patent example 1 and specification example 1) are shaped and sized (e.g. spherical and about 2-15 micron diameter) as particles disclosed in the present specification(e.g, see columns 2 and 7 of the reference and compare to specification page 7 and specification figure 2); and c. In light of the specification disclosure which teaches that a composite particle containing a metal (e.g., copper) "core" coated with a copper pyrithione "shell" results upon aqueous mixing a copper compound and a pyrithione salt (e.g.

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sodium pyrithione as found in both the reference and specification example) followed by the precipitation protocol. Where the claimed and prior art products are identical or substantially identical in structure or composition (as in the present case) AND/OR is produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the appellant and the prior art are the same, the appellant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). For a chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical or substantially identical chemical structure, the properties appellant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP 2112.01. The PTO lacks the facilities for making comparisons between prior art and claimed compositions.

Response to Arguments

Applicants acknowledge that Hosseini et al. relates to a process for producing a gel-free dispersion or solution of copper pyrithione employing at least one surfactant. Applicants

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further acknowledge that the working examples of Hosseini et al. relate to the preparation of copper pyrithione. But argue that there is no suggestion in Hosseini et al of a composite particle having a core consisting essentially of surface oxidized copper power, cuprous oxide, copper hydroxide and combinations thereof as recited in instant claims.

In reply, attention is drawn to Hosseini at e.g., Background of the invention wherein Hosseini discloses the well-known composition comprising pyrithione salt plus copper salt (e.g., cuprous oxide). Hosseini states:

Pyrithione salts are well-known salts useful in a wide variety of applications....For example, paints containing a pyrithione salt.. plus a copper salt (e.g. cuprous oxide ...) are known in the art, as disclosed, for example, in U.S. Pat. No. 5,057,153. U.S. Pat. No. 5,185,033 describes a process for making a paint or paint base containing copper pyrithione or pyrithione disulfide plus cuprous oxide, wherein the paint exhibits stability against gelation during storage. U.S. Pat. No. 5,246,489 discloses a process for providing in situ generation of copper pyrithione in a paint or paint base which comprises incorporating a metal salt of pyrithione, cuprous oxide....

Copper pyrithione itself is now being considered for use in supplementing or supplementing or supplanting zinc pyrithione in view of the fact that copper pyrithione is more favored from a low-toxicity standpoint and provides stability against gelation in products such as paint during storage prior to use....

New processes for producing copper pyrithione while avoiding this gellation or thickening problem during production of the copper pyrithione solution or dispersion would be highly desired by the biocides manufacturing community. The present invention provides such solution.

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Thus, the working examples of Hosseini, as applicants acknowledge is shown for the well known copper pyrithione composition.

Applicants submit that the composite particles recited in the instant claims and the copper pyrithione particles disclosed in Hosseini et al. have different chemical structures because they are made from different copper compounds having different solubility. Specifically, Applicants' claimed composite particles are produced from substantially insoluble copper compounds such as surface oxidized copper power, cuprous oxide, copper hydroxide and/or combinations thereof. During the transchelation reaction, these copper compounds are present as particles suspended in the reaction carrier as they are substantially insoluble. Under the reaction conditions of the present invention, some of the pyrithione anions from the soluble pyrithione salt or pyrithione acid chelate with the metal copper on the surface of these copper compound containing particles, thus forming a composite particle with a core of copper, cuprous oxide or copper hydroxide and a shell of copper pyrithione. The structure of the composite particle formed is confirmed by microscopic analysis and is shown at Fig. 2 of the present application. In contrast, the Hosseini particles are made from a copper salt that is soluble in the reaction carrier.

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(see Hosseini, col. 2, lines 59-60). Since the copper salt disclosed in Hosseini is soluble, in the reaction mixture, it exists as anions and cations separated by numerous solvent molecules, ions from the pyrithione salt and/or surfactants. Under the reaction conditions of the Hosseini process, copper pyrithione is formed from copper cations and pyrithione anions. Since copper pyrithione is highly insoluble, once it is formed, copper pyrithione precipitates out from the reaction mixture. The anions and cations of the copper salt, on the other hand, stay in the reaction mixture and are removed when the precipitate (copper pyrithione) is filtered and washed with plenty amount of solvent. Therefore, by utilizing soluble copper salts disclosed in Hosseini as the substrate in the chelation reaction, no composite particles are formed, but rather discrete particles of copper pyrithione. Accordingly, Hosseini does not disclose any composite particles, much less a composition containing such composite particles as recited in the instant claims. In fact, Hosseini et al. teaches away from making any composite particles because the Hosseini reference specifically teaches the use of a soluble copper salt to prepare copper pyrithione. A person of ordinary skill in the art will appreciate that the purpose of this limitation is to ensure a

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complete removal of the soluble copper salt in the later work up process.

In reply, Hosseini teaches a biocidal composition comprising of the same components as claim. The arguments as to the process of producing the instant claim particles are not commensurate in scope with the claims which recite only composition, the components of which are known in the art. As applicants stated above, insoluble pyrithione still reacted with copper (and precipitated out) even in small amount. Thus this is sufficient to meet the claim composition. It is well settled law that patentability of a compound/composition does not depend on the method by which the compound/composition is made.

Claims 2, 4, 6-9,11 and 41, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hosseini et al. '860 alone or in view of the specification (e.g. page 7, figures (e.g. fig. 2) and examples (e.g. example 1) to demonstrate inherency and Gavin et al. US Pat. 5,342,437 (8/94). The substance of the 102/103 rejection of claims 2, 4 and 6-9 over Hosseini et al. alone or in view of the specification is herein incorporated by reference in its entirety. The Hosseini et al. particles differ from composition of claim 11 and claim 41 by failing to teach utilizing a "fatty acid coating" (e.g. stearic,

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linoleic, oleic etc.). In this regard, Hosseini et al. Reference (e.g. see col. 1) teaches that pyrithione salts in the form of crystals (e.g., platelets) are incorporated into manufacturing articles including paints (e.g., coating compositions); with the problem of "gellation" during the production of copper pyrithione solution or dispersion occurring. The Hosseini solution to the gellation problem is to "surfactant coat" its copper pyrithione particles. However Gavin et al. teach that incorporating fatty acids (e.g., stearic, linoleic, oleic etc.) into its pyrithione compositions (e.g. zinc pyrithione/cuprous oxide) prior to incorporation into manufacturing articles (e.g. coating compositions such as paints) solves the gellation problem. Accordingly, one of ordinary skill in the art at the time of applicant's invention would be motivated to apply a "fatty acid" particle coat, in addition or, in lieu of the "surfactant coat" in order to address the gellation problem. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Hosseini et al. reference particle to apply a "fatty acid" coat in light of the Gavin reference teaching that to do so would address the gellation problem recognized by both the Hosseini and Gavin references.

Response to Arguments

Applicants recognize that Gavin et al disclose the incorporation of fatty acids into pyrithione-containing paint compositions in order to avoid gelation. But argue that Gavin et al. do not teach or suggest composite particles of any kind, much less of composite particles coated with a fatty acid as claimed in instant claims 41 and 11.

In response, Gavin is employed not for the purpose as argued since the composition comprising copper-containing compound and pyrithione is taught by Hosseini. Gavin is employed for the advantage in the used of fatty acid and provides the motivation to one having ordinary skill in the art to do so.

One cannot show non-obviousness by attacking the references individually where the rejection is based on a combination of references. *In re Young*, 159 USPQ 725 (CCPA 1968). When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR International Co. v. Teleflex Inc.*, 550 USPQ2d 1385 (2007).

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Claims 2, 4, 6-9, 35-36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hosseini et al. '860 alone or in view of the specification (e.g. page 7, figures (e.g. fig. 2) and examples (e.g. example 1) to demonstrate inherency and Kappock et al (US Pat. 5,518,774) (5/96). The substance of the 102/103 rejection of claims 2, 4 and 6-9 over Hosseini et al. alone or in view of the specification is herein incorporated by reference in its entirety. The Hosseini et al. spherical particles differ from the presently claimed invention by failing to explicitly teach: (a). selection of "copper oxide" as the metal ion containing compound for use with the pyrithione salt to form copper pyrithione (claim 35); and (b). Copper oxide/copper pyrithione ratio of 5:1 to 15:1 or 10:1 with a "diameter of the coating material" about 1% of the "idealized spherical particle". (claims 36 and 37). Kappock et al. teach that "transchelation" of a soluble pyrithione salt (such as sodium pyrithione) with a metal ion-containing compound to form insoluble pyrithione salts afford an excellent combination "in can" and "dry film" antimicrobial protection to an aqueous coating (e.g., paint) composition. (E.g. see col. 2, lines 30-40). Preferred metals include copper in the form of "copper oxide" or "copper sulfate" with a copper oxide/copper pyrithione ratio of "between about 1:10 and about 10:1"; in which the

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amount of metal ion compound can vary (e.g..001% or lower to 10% or greater, preferably between 0.005% and 1%) and include optimization so as to enable complete conversion of the pyrithione salt by transchelation to metal pyrithione during storage of the coating composition. See Kappock et al. Col. 2-3, especially col. 3, lines 12-32; patent claims 4-8. Accordingly, the Kappock reference would provide motivation to one of ordinary skill in the art to modify the Hosseini copper pyrithione solid particle (e.g. for use in a coating composition such as paint) by substituting copper oxide for the Hosseini copper salt (e.g. copper sulfate: col. 2, lines 58-66) since: a). The references' teaching of functional equivalency of copper oxide and copper sulfate since both references teach copper sulfate but Kappock further utilized copper oxide; and b). In view of the benefits taught by the Kappock reference of utilizing copper oxide e.g. excellent combination "in can" and "dry film" antimicrobial protection to an aqueous coating (e.g. paint) composition. Similarly, the Kappock reference provides one of ordinary skill in the art with copper oxide/copper pyrithione ratios (e.g., about 10:1) with additional motivation to optimize (e.g. enable complete conversion of the pyrithione salt to metal pyrithione) to achieve amounts within the scope of the presently claimed invention of 5:1 to 15:1 or 10:1 with a

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"diameter of the coating material" about 1% of the "idealized spherical particle". Thus it would have been *prima facie* obvious to one of ordinary skill in the art to modify the Hosseini et al. spherical particles by a). selecting "copper oxide" as the metal ion containing compound for use with the pyrithione salt to form copper pyrithione (claim 35); and b). utilize copper oxide/copper pyrithione ratio of 5:1 to 15:1 or 10:1 within the scope of the presently claimed invention (e.g., claims 35-36 and 41). Regarding the claimed limitation "diameter of the coating material" about 1% of the "idealized spherical particle" (claims 36 and 37) it is noted that: a). Modification of the Hosseini et al. reference in view of the Kappock reference teaching would result in the "spherical particles" which contain the same components in the same amounts as the presently claimed invention which are made in an analogous manner. In this regard, it is noted that where the claimed and prior art products are identical or substantially identical in structure or composition (as in the present case) AND/OR is produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the appellant and the prior art are the same, the appellant has the

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burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). For a chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical or substantially identical chemical structure, the properties appellant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP 2112.01. The PTO lacks the facilities for making comparisons between prior art and claimed compositions.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP 2144.05.

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When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. . When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art elements according to their established functions." KSR International Co. v. Teleflex Inc., 550 USPQ2d 1385 (2007).

Response to Arguments

Applicants state that the Hosseini reference which is discussed in more detail above, teaches gel free copper pyrithione particles formed by reacting soluble pyrithione salt and soluble copper salt in an ion- exchange reaction. Kappock et al. teaches transchelation of copper oxide with a soluble pyrithione salt to produce an insoluble pyrithione salt such as copper pyrithione in a formulated paint composition to provide in-can preservation during storage of the paint. (See col. 3, lines 12-32). Applicants further recognize that it is well known that copper oxide is an insoluble compound. But argue that there is no motivation for a person skilled in the art to substitute the soluble copper compound required by Hosseini et al. process with an insoluble copper compound such as copper oxide disclosed

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in Hosseini et al. Doing so will be against the specific teachings of Hosseini et al.

In reply, whether the known composition is insoluble or soluble is immaterial to the known composition, especially since the form by which the compositions, as known in the art, can be in soluble or insoluble form. The preferential form in which it exists would depend upon the purpose for which one intends said known composition.

Applicants further argue that in addition, Kappock et al. disclose the use of copper oxide and copper sulfate in the patentee's composition. Applicants respectfully submit that copper oxide normally refers to copper (II) oxide, which differs from cuprous oxide. Accordingly, Kappock et al. does not disclose or suggest any of the core materials recited in the composite particles, namely, cuprous oxide, surface oxidized copper powder, copper hydroxide, and combinations thereof.

In response, the prior art teaches that either cuprous oxide as taught by Hosseini or copper oxide as taught by Kappock (the claim recites copper powder, which reads on copper) can be used as the same composition of copper pyrithione is formed.

When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art

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elements according to their established functions." KSR

International Co. v. Teleflex Inc., 550 USPQ2d 1385 (2007).

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TERESA WESSENDORF/

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